# 510(k) Summary: K120984

APR 2 6 2013

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| **Submitter:** | Masimo Corporation<br>40 Parker<br>Irvine, CA 92618<br>Phone: (949) 297-7000<br>FAX: (949) 297-7592 |
| **Contact:** | Patricia Milbank<br>Vice President, Regulatory Affairs |
| **Date Summary Prepared:** | April 23, 2013 |
| **Trade Name:** | Masimo Acoustic Monitoring Sensors (adult/pediatric) |
| **Common Name:** | Pulse Oximeter |
| **Classification Name:** | DQA – Oximeter (870.2700)<br>BZQ – Breathing frequency monitor (868.2375) |
| **Predicate Device:** | K091241 – Masimo Rainbow SET® Rad-87 Pulse CO-Oximeter and Masimo Acoustic Monitoring Sensor (adult) |

## Description of the Device

The Masimo Acoustic Monitoring Sensor is a single-patient use device consisting of a piezoelectric sensor element and an adhesive strip that is attached to the patient's neck for the purpose of noninvasive respiratory rate monitoring in adult and pediatric patients (> 10 kg). As with the predicate Masimo Acoustic Monitoring Sensor (model RAS-125 for adults only), the RAS-125c for pediatric patients is intended to be attached via cable to a pulse oximeter monitor incorporating the Masimo Rainbow® Acoustic Monitoring™ technology to provide a continuous display of the patient's acoustic respiratory rate. Suitable pulse oximeter monitors include the previously cleared Radical 7 and Rad 87 devices.

## Indications for Use

The Rainbow® Acoustic Monitoring™ sensors and cables are indicated for continuous, noninvasive monitoring of respiratory rate (RRa™).
The RAS-125 is indicated for adult patients in hospitals, hospital-type facilities, mobile and home environments.
The RAS-125c is indicated for adult and pediatric patients in hospitals, hospital-type facilities, mobile and home environments.

**Contraindications**

The RAS-125 and RAS-125c sensors are contraindicated in patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

**Results from Clinical Studies**

Accuracy data was obtained from a comparison of a manual count of respiratory rate in healthy adult subjects and in hospitalized pediatric subjects for whom post-operative monitoring of respiratory rate was indicated.

Respiration rate accuracy for the Rainbow Acoustic Monitoring sensor and instrument has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation was performed with the RAS-125 and RAS-125c sensors and instrument for up to 30 breaths per minute in adult subjects >30 kg, and up to 50 breaths per minute in hospitalized pediatric subjects, age 2 years or older and >10kg.

| | **RAS-125** | **RAS-125c** |
|---|---|---|
| Body Weight | Adult > 30 kg | Adult, Pediatric > 10 kg |
| Application Site | Neck | Neck |
| Breaths per Minute, Accuracy Range* | 4 to 70 ± 1 breath per minute | 4 to 70 ± 1 breath per minute |

The accuracy of this device has not been validated for monitoring of respiratory rate in patients with specific medical conditions, e.g., asthma, COPD or cystic fibrosis. Accuracy of the sensor has not been validated in infants or neonates.

**Test Summary**

The RAS-125 and RAS-125c sensors comply with the voluntary standards as detailed in Section 9 of this submission and the following quality assurance, verification and validation measures were included in the development process:

- Design control activities per 21 CFR 820
- Risk analysis and risk management activities per ISO 14971
- Software verification and validation testing per 21 CFR 820 and the applicable FDA guidance documents (General Principles of Software Validation, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and Off-The-Shelf Software Use in Medical Devices)
- Biocompatibility testing per EN ISO 10993 for patient skin contacting, prolonged duration materials, including cytotoxicity, skin irritation and sensitization
- Environmental testing (operating temperature, humidity, fluid ingress), safety and mechanical testing per ISO 9919
- Electromagnetic compatibility per IEC 60601-1-2
- Electrical safety testing per IEC 60601-1
- Two non-randomized clinical validation studies in healthy adult volunteers (n=26) and

hospitalized post-surgical adult subjects (n=26)

- A non-randomized clinical validation study in hospitalized post-surgical pediatric subjects (n=26), conducted at 3 hospital centers in the United States

**Conclusion**

The information in this 510(k) submission demonstrates that the Masimo RAs-125 and RAS-125c Acoustic Respiration Sensors are substantially equivalent to the predicate device, with respect to safety, effectiveness, and performance, when used in adult and pediatric patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Ms. Patricia Milbank
Vice President, Regulatory Affairs
Masimo Corporation
40 Parker
IRVINE CA 92618

Re: K120984
Trade/Device Name: Masimo Acoustic Respiration Sensor (Adult/Pediatric)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, BZA
Dated: March 13, 2013
Received: March 14, 2013

Dear Ms. Milbank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.04.26 07:26:55 -04'00'

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** K120984

**Device Name:** Masimo Acoustic Respiration Sensor (Adult/Pediatric)

Indications for Use:

The Rainbow® Acoustic Monitoring™ sensors and cables are indicated for continuous, noninvasive monitoring of respiratory rate (RRa™).
The RAS-125 is indicated for adult patients in hospitals, hospital-type facilities, mobile and home environments.
The RAS-125c is indicated for adult and pediatric patients in hospitals, hospital-type facilities, mobile and home environments.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chan O. Lee -S
2013.04.25 14:13:49 -04'00'
For LS

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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